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TRANSMITTAL LETTER TO THE UNITED STATES 015058-005110US DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A FILING UNDER 35 U.S.C. 371** PRIORITY DATE CLAIMED INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE 11 December 2003 PCT/US2004/041580 10 December 2004 TITLE OF INVENTION Use of Cathepsin S Inhibitors for Treating an Immune Response Caused by Administration of a Small Molecule Therapeutic or Biologic APPLICANT(S) FOR DO/EO/US ELROD, Kyle C. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). 5. A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. is attached hereto (required only if not communicated by the International Bureau). b. has been communicated by the International Bureau. c. X is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. is attached hereto. b. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. are attached hereto (required only if not communicated by the International Bureau). b. have been communicated by the International Bureau. c. have not been made; however, the time limit for making such amendments has NOT expired. d. A have not been made and will not be made. 8. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. 14. A substitute specification.

A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.

A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

A second copy of the published International Application under 35 U.S.C 154(d)(4).

A power of attorney and/or change of address letter.

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| U.S. APPLICATION NO, (if known, see 37 CFR 1.5) | | | INTERNATIONAL APPLICATION NO. | | ATTORNEY'S DOCKET NUMBER | | | |
|---|--|---|-------------------------------|--|--------------------------|-----------------------|------------------------|--------------|
| To selestigned 1 | | | 9 / / PCT/US2004/041580 | | 015058-005110US | | | |
| 20. Other items or information: Express Mail Label No. EV 336 070 908 US, mailed on June 6, 2006 | | | | | | | | |
| | 1) International Publication No. WO 2005/058348 A1 2) International Search Report and the Written Opinion | | | | | | | |
| 3) PCT Forms: PCT/IB/301; PCT/IB/304; PCT/IB/308 | | | | | | | | |
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| The | following | fees have been s | ubmitted | | | | CALCULATIONS | PTO USE ONLY |
| 21. 🛭 Ba | isic nationa | al fee (37 CFR 1.4 | 192(a)) | | \$: | 300 | \$ 300 | |
| 22. X Examination fee (37 CFR 1.492(c)) | | | | | | | | |
| If the written o | f the written opinion prepared by ISA/US or the international preliminary examination report prepared \$200 | | | | | | | |
| by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 All other situations\$200 | | | | | | | | |
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| 23. Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by | | | | | | | | |
| IPEA/U | IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 | | | | | | | |
| Internat | Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority | | | | | | | |
| International S | Search Rep sly commu | ort prepared by a nicated to the US | an ISA othe S by the IB | er than the US and provide | ed to the Of \$ | fice or 400 | £400 | |
| previously communicated to the US by the IB \$400 All other situations \$500 | | | | | | | \$400 | |
| TOTAL OF 21, 22 and 23 = | | | | | | | \$ 900 | |
| Addition | al fee for sp | pecification and di | awings file | d in paper over 100 sheets R 1.821(c) or (e) or compute | (excluding | listing in an | | |
| elec | tronic med | ium) (37 CFR 1.4 | 92(j)). | ,, ,, , | | noung m an | | |
| The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | | | · | |
| Total Sheets Ext | | a Sheets Number of each additional 50 or fraction RATE thereof (round up to a whole number) | | | | | | |
| | 121 | 21 | 1 250 | | | | | |
| Complete of \$420.00 for formishing any of the except for examination for or the eath or declaration | | | | | | | | |
| after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | | | | | |
| CLAIMS | | NUMBER FILED | | NUMBER EXTRA RATE | | | | <u> </u> |
| Total claims | | 25 - 20 | | x \$ 50 | | | \$ | |
| Independent claims | | 6- 3 = | | 3 × \$200 | | | \$ 600 | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 | | | | | | | \$ 360 | |
| TOTAL OF ABOVE CALCULATIONS = \$1210 | | | | | | | | |
| Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½. | | | | | | | | |
| SUBTOTAL = | | | | | | | \$.1210 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | | | | | |
| | | \$ 2110 | | | | | | |
| | Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | | | | |
| TOTAL FEES ENCLOSED = | | | | | | | \$ 2110 | |
| | | | | | | | Amount to be refunded: | \$ |
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| a. | | A check in the amount of \$ | to cover the abov AP20 Rec'd PCT/PTO 36 JUN 200 | | | | | | |
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| b. | \boxtimes | Please charge my Deposit Account No. <u>20-1430</u> in the amount of <u>\$ 2110</u> to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | | | |
| C. | \boxtimes | The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>20-1430</u> . A duplicate copy of this sheet is enclosed. | | | | | | | |
| d . | | Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | | | | | |
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| SEI | IA DI | LL CORRESPONDENCE TO: | SIGNATURE SIGNATURE | | | | | | |
| Will | iam E | 3. Kezer | Melling D. Kong | | | | | | |
| TOWNSEND AND TOWNSEND AND CREW LLP | | | William B. Kezer | | | | | | |
| Two | Emb | parcadero Center, Eighth Floor | 37.369 | | | | | | |
| San Francisco, CA 94111-3834 | | | REGISTRATION NUMBER | | | | | | |
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